the present request is governed by 37 CFR § 1.607.3

(2) Proposed Count

The following count is proposed in accordance with 37 CFR §1.607(a)(2):

Count 1: A longitudinally flexible stent for implanting in a body lumen, comprising;

- a first cylindrically shaped element, a second cylindrically shaped element, a third cylindrically shaped element, up to an Nth cylindrically shaped element, the cylindrically shaped elements being generally independently expandable in the radial direction and generally aligned on a common longitudinal axis;
- other than the first and the Nth cylindrically shaped elements, each of the cylindrically shaped elements has two adjacent cylindrically shaped elements spaced in opposite axial directions;
- each of the cylindrically shaped elements having an undulating pattern of peaks and valleys, the undulating pattern of each of the cylindrically shape elements being out of phase with the undulating pattern of each of the adjacent cylindrically shaped elements; and
- each of the cylindrically shaped elements being interconnected to one of the adjacent cylindrically shaped elements so that the cylindrically shaped elements form a longitudinally flexible stent.

(3) Patentee's Claims Corresponding to the Count

The claims in the Lau patent that correspond to the proposed count are 1-8.

(4) Applicant's Claims Corresponding to the Count

Applicant has presented claims 5-12 that correspond to the proposed count.

³ § 1.608 is limited to the opposite situation in which the patentee has an earlier effective date.

Since these claims do not utilize the exact language of the count (does not "correspond exactly" to the proposed count), the following explanation is provided in accordance with 37 CFR § 1.607(a)(4).

In order to declare an interference, "interference-in-fact" must be demonstrated. An interference-in-fact exists when the claimed invention of Party A anticipates or renders obvious the claimed invention of Party B <u>and</u> the claimed invention of Party B anticipates or renders obvious the claimed invention of Party A. Winter v. Fujita, 53 USPQ2d 1234 (Bd. Pat. App. & Intf. 1999). As can be seen from the following tabulation, Applicant's claims would anticipate or render obvious the claimed invention of Lau under the hypothetical assumption set forth in 37 CFR §1.601(n) and conversely the claimed invention of Lau would anticipate or render obvious the claimed invention of Applicant:

U.S. Patent No. 6,066,167	Applicant Claims
1. A longitudinally flexible stent for implanting in a body lumen, comprising;	A linearly flexible stent for im- planting within a body vessel com- prising:
a first cylindrically shaped element, a second cylindrically shaped element, a third cylindrically shaped element, up to an Nth cylindrically shaped element, the cylindrically shaped elements being generally independently expandable in the radial direction and generally aligned on a common longitudinal axis;	at least three turns defining a generally cylindrical body, the turns being generally independently expandable in the radial direction and generally aligned on a common longitudinal axis;
other than the first and the Nth cylindrically shaped elements, each of the cylindrically shaped elements has two adjacent cylindrically shaped	each of the turns other than the first and the last having two adjacent turns spaced in opposite axial directions

⁴ Throughout this request, Applicant uses the term "anticipation" exclusively with reference to the hypothetical assumption set forth in 37 CFR §1.601(n).

each of the cylindrically shaped elements being interconnected to one of the adjacent cylindrically shaped elements being interconnected to one of the adjacent cylindrically shaped elements being interconnected to one of the adjacent cylindrically shaped elements so that the cylindrically shaped elements form a longitudinally flexible stent. 2. The stent of claim 1, wherein the distance between adjacent cylindrically shaped elements includes at least three peaks and three valleys. 3. The stent of claim 1, wherein each of the cylindrically shaped elements includes at least three peaks and three valleys. 4. The stent of claim 1, wherein the peaks and valleys have a substantially U-shaped configuration. 5. A longitudinally flexible stent for implanting in a body lumen, comprising; a first cylindrically shaped element, a third cylindrically shaped element, the cylindrically shaped elements being generally aligned on a common longitudinal axis; each of the cylindrically shaped element, axis; each of the turns defining a generally cylindrical body independently expandable in the radial direction and generally aligned on a common longitudinal axis;		
each of the cylindrically shaped elements having an undulating pattern of each of the cylindrically shaped elements being out of phase with the undulating pattern of each of the cylindrically shaped elements being out of phase with the undulating pattern of each of the adjacent cylindrically shaped elements; and each of the cylindrically shaped elements being interconnected to one of the adjacent cylindrically shaped elements form a longitudinally flexible stent. 2. The stent of claim 1, wherein the distance between adjacent cylindrically shaped elements is less than the width of either a single peak or a single valley. 3. The stent of claim 1, wherein the distance between adjacent cylindrically shaped elements includes at least three peaks and three valleys. 4. The stent of claim 1, wherein each of the cylindrically shaped elements includes at least three peaks and three valleys. 4. The stent of claim 1, wherein the peaks and valleys have a substantially U-shaped configuration. 5. A longitudinally flexible stent for implanting in a body lumen, comprising; a first cylindrically shaped element, a second cylindrically shaped element, up to an Nth cylindrically shaped element, the cylindrically shaped element, as econd cylindrically shaped element, the cylindrically shaped element, as third cylindrically shaped element, the cylindrically shaped element, as third cylindrically shaped element, as generally independently expandable in the radial direction and generally aligned on a common longitudinal axis;	U.S. Patent No. 6,066,167	Applicant Claims
elements having an undulating pattern of peaks and valleys, the undulating pattern of each of the cylindrically shape elements being out of phase with the undulating pattern of each of the adjacent cylindrically shaped elements being interconnected to one of the adjacent cylindrically shaped elements being interconnected to one of the adjacent cylindrically shaped elements so that the cylindrically shaped elements form a longitudinally flexible stent. 2. The stent of claim 1, wherein the distance between adjacent cylindrically shaped elements is less than the width of either a single peak or a single valley. 3. The stent of claim 1, wherein each of the cylindrically shaped elements includes at least three peaks and three valleys. 4. The stent of claim 1, wherein the peaks and valleys have a substantially U-shaped configuration. 5. A longitudinally flexible stent for implanting in a body lumen, comprising; a first cylindrically shaped element, up to an Nth cylindrically shaped element, up to an Nth cylindrically shaped element, the cylindrically shaped element, the cylindrically shaped element, up to an Nth cylindrically shaped elements being generally independently expandable in the radial direction and generally aligned on a common longitudinal axis;		
elements being interconnected to one of the adjacent cylindrically shaped elements so that the cylindrically shaped elements form a longitudinally flexible stent. 2. The stent of claim 1, wherein the distance between adjacent cylindrically shaped elements is less than the width of either a single peak or a single valley. 3. The stent of claim 1, wherein each of the cylindrically shaped elements includes at least three peaks and three valleys. 4. The stent of claim 1, wherein the peaks and valleys have a substantially U-shaped configuration. 5. A longitudinally flexible stent for implanting in a body lumen, comprising; a first cylindrically shaped element, a second cylindrically shaped element, at third cylindrically shaped element, up to an Nth cylindrically shaped elements being generally independently expandable in the radial direction and generally aligned on a common longitudinal axis;	elements having an undulating pattern of peaks and valleys, the undulating pattern of each of the cylindrically shape elements being out of phase with the undulating pattern of each of the adjacent cylindri-	generally cylindrical body having an undulating pattern of zigzags or waves, each of the turns defining a generally cylindrical body being out of phase with the undulating pattern of each of the adjacent turns defining a generally cy-
distance between adjacent cylindrically shaped elements is less than the width of either a single peak or a single valley. 3. The stent of claim 1, wherein each of the cylindrically shaped elements includes at least three peaks and three valleys. 4. The stent of claim 1, wherein the peaks and valleys have a substantially U-shaped configuration. 5. A longitudinally flexible stent for implanting in a body lumen, comprising; a first cylindrically shaped element, a second cylindrically shaped element, up to an Nth cylindrically shaped element, up to an Nth cylindrically shaped element, the cylindrically shaped element, the cylindrically shaped element, the cylindrically shaped element, the cylindrically shaped element being generally independently expandable in the radial direction and generally aligned on a common longitudinal axis;	elements being intercon- nected to one of the adjacent cylindrically shaped elements so that the cylindrically shaped elements form a lon-	cylindrical body being inter- connected to one of the adja- cent turns so that the turns defining a generally cylindrical body form a longitudinally
of the cylindrically shaped elements includes at least three peaks and three valleys. 4. The stent of claim 1, wherein the peaks and valleys have a substantially U-shaped configuration. 5. A longitudinally flexible stent for implanting in a body lumen, comprising; a first cylindrically shaped element, a second cylindrically shaped element, a third cylindrically shaped element, up to an Nth cylindrically shaped element, the cylindrically shaped element, the cylindrically shaped elements being generally independently expandable in the radial direction and generally aligned on a common longitudinal axis; of the turns defining a generally cylindrical body includes at least three peaks and three valleys. 8. The stent of claim 5, wherein the peaks and valleys have a substantially U-shaped configuration. 9. A longitudinally flexible stent for implanting in a body lumen, comprising; at least three turns defining a generally independently expandable in the radial direction and generally aligned on a common longitudinal axis;	distance between adjacent cylindri- cally shaped elements is less than the width of either a single peak or	distance between adjacent turns defining a generally cylindrical body is less than the width of either a
peaks and valleys have a substantially U-shaped configuration. 5. A longitudinally flexible stent for implanting in a body lumen, comprising; a first cylindrically shaped element, a second cylindrically shaped element, a third cylindrically shaped element, up to an Nth cylindrically shaped element, the cylindrically shaped elements being generally independently expandable in the radial direction and generally aligned on a common longitudinal axis; peaks and valleys have a substantially U-shaped configuration. 9. A longitudinally flexible stent for implanting in a body lumen, comprising; at least three turns defining a generally independently expandable in the radial direction and generally aligned on a common longitudinal axis;	of the cylindrically shaped elements includes at least three peaks and	of the turns defining a generally cy- lindrical body includes at least three
planting in a body lumen, comprising; a first cylindrically shaped element, a second cylindrically shaped element, a third cylindrically shaped element, up to an Nth cylindrically shaped element, the cylindrically shaped elements being generally independently expandable in the radial direction and generally aligned on a common longitudinal axis; implanting in a body lumen, comprising; at least three turns defining a generally cylindrical body, the turns being generally independently expandable in the radial direction and generally aligned on a common longitudinal axis;	peaks and valleys have a substan-	peaks and valleys have a substan-
second cylindrically shaped element, a third cylindrically shaped element, up to an Nth cylindrically shaped element, the cylindrically shaped elements being generally independently expandable in the radial direction and generally aligned on a common longitudinal axis;	planting in a body lumen, compris-	implanting in a body lumen, com-
each of the cylindrically shaped each of the turns having an un-	second cylindrically shaped element, a third cylindrically shaped element, up to an Nth cylindrically shaped element, the cylindrically shaped elements being generally independently expandable in the radial direction and generally aligned on a common longitudinal	ally cylindrical body, the turns being generally independently expandable in the radial direction and generally aligned on a common longi-
	each of the cylindrically shaped	each of the turns having an un-

† . •

U.S. Patent No. 6,066,167	Applicant Claims	
elements having an undulating pattern of peaks and valleys, the undulating pattern of each of the cylindrically shaped elements being out of phase with the undulating pattern of each of the adjacent cylindrically shaped elements; and	dulating pattern of peaks and valleys, the undulating pattern of each turn being out of phase with the undulating pattern of each of the adjacent turns; and	
each of the cylindrically shaped elements being interconnected to one of the adjacent cylindrically shaped elements so that the cylindrically shaped elements form a longitudinally flexible stent.	each of the turns being intercon- nected to one of the adjacent turns so that the turns defining a generally cylindrical body form a longitudinally flexible stent.	
6. The stent of claim 5, wherein the distance between adjacent cylindrically shaped elements is less than the width of either a single peak or a single valley.	ance between adjacent cylindri- y shaped elements is less than defining a generally cylindrical bod width of either a single peak or is less than the width of either	
 7. The stent of claim 5, wherein each of the cylindrically shaped elements includes at least three peaks and three valleys. 11. The stent of claim 9, whe each of the turns defining a gerally cylindrical body includes least three peaks and three valles 		
8. The stent of claim 5, wherein the peaks and valleys have a substantially U-shaped configuration.	12 The stent of claim 9, wherein the peaks and valleys have a substantially U-shaped configuration.	

As will be seen from the following analysis {which also applies Applicant's claims 5-12 to his disclosure in accordance with 37 CFR § 1.607(a)(5)(ii)}, the claims of Lau and those of Applicant are an anticipation of each other or at very least render each other obvious.⁵

⁵ A copy of claims 5-12 showing relevant disclosure by page and line is shown in annexed Appendix 1.

First Limitation:6

Lau's claim 1 defines a longitudinally flexible stent for implanting in a body lumen while Applicant's claim 5 defines a linearly flexible stent for implanting within a body vessel. A body lumen is a body vessel (such as an artery). {See; e.g., Lau, col. 1, lines 18-22}.

Applying the terms of Applicant's claim 5 to the disclosure of the application under 37 CFR § 1.607(a)(5)(ii), it is disclosed on page 1, lines 22-25, that the invention is particularly useful in transluminar implantation of a stent in the field of cardiology and especially in the case of coronary angioplasty to prevent restenosis. On page 4, lines 5 and 6, of the present specification, it is noted that prior art stents did not satisfy the requirement of being flexible longitudinally throughout its length. On page 6, line 30, reference is made to the advantage of linear flexibility. On page 7, lines 1-4, it is disclosed that a major object of the invention is a preformed flexible wire stent which allows easy radial expansion and subsequent retention of the radially expanded shape well anchored within a vessel.

Second Limitation:

Lau's claim 1 calls for a first cylindrically shaped element, a second cylindrically shaped element, a third cylindrically shaped element, up to an Nth cylindrically shaped element. These cylindrically shaped elements are independently expandable in the radial direction and aligned on a common longitudinal axis. Applicant claim 5 recites at least three turns defining a generally cylindrical body, the turns being generally independently expandable in the radial direction and generally aligned on a common longitudinal axis;

Applying these terms to the disclosure of the application under 37 CFR §

⁶ While technically not a limitation since it precedes "comprising", this language is addressed here for completeness' sake.

1.607(a)(5)(ii)}, Applicant discloses from page 5, line 27, through page 6, line 12, that one creates a two dimensional zigzag which is wound into a cylindrical shape, *i.e.*, providing a plurality of turns defining a generally cylindrical body. It is further disclosed on page 5, lines 18-22, that the stent can be expanded radially to a diameter larger than initially introduced so that starting with a wire diameter of .008 and initial stent diameter of .075, a ratio of 2½:1 can be achieved. Figs. 1-8 all depict at least three turns; *i.e.*, a plurality. Figs. 9-12 show independently expansion of the turns.

Third Limitation:

Lau's claim 1 further states that other than the first and the last ("Nth") elements, each has two adjacent cylindrically shaped elements spaced in opposite axial directions.

Applicant's claims specify that each of the turns other than the first and the last having two adjacent turns spaced in opposite axial directions. It appears this simply refers to the repetition of the elements along the longitudinal axis.

Applying the terms of Applicant's claim 5 to the disclosure of the application under 37 CFR § 1.607(a)(5)(ii)}, each of the drawing, including Fig. 8,shows two adjacent turns spaced in opposite directions along the longitudinal axis.

Fourth Limitation:

Lau's claim 1 further states that each of the cylindrically shaped elements has an undulating pattern of peaks and valleys, the undulating pattern being out of phase with the undulating pattern of each of the adjacent elements.

Applicant's claim 5 specifies that each of the turns defining the generally cylindrical body have an undulating pattern of zigzags or waves, each of the turns defining a generally cylindrical body being out of phase with the undulating pattern of each of the adjacent turns defining a generally cylindrical body.

Applying the terms of Applicant's claim 5 to the disclosure of the application

under 37 CFR § 1.607(a)(5)(ii)}, page 5, lines 30-33 makes specific reference to a sinusoidal form (also referred to as a "zigzag") while on page 6, beginning at line 7, reference is made to then forming a cylindrical shape from the zigzag.

The significance of whether the peaks are "out of phase" or "in phase" is not apparent. In fact, Lau discloses that the zigzag patterns preferably are "in phase" {see, col. 2, line 44-47}. The "in phase"/"out of phase" distinction appears to be nothing more that a matter of mechanical design choice, Lau specifically noting that the particular pattern and number of undulations:

...are chosen to fill particular mechanical requirements for the stent such as radial stiffness. {Col. 5, line 64 through col. 6, line 6}

In any event, Applicant discloses both possibilities. Thus Fig. 7 shows the peaks of the zigzag circumferentially aligned ("in phase") while Fig. 8 shows the zigzags "out of phase" with each of the adjacent turns; note the "phase" of the opposed peaks and valleys at **50** and **48**. While Lau may have had some specific orientation in mind, the phrase he used, "out of phase", simply requires different phases.

Fifth Limitation:

Lau's claim 1 finally specifies that each of the cylindrically shaped elements is interconnected to one of the adjacent cylindrically shaped elements so that the cylindrically shaped elements form a longitudinally flexible stent.

Applicant's claim 5 specifies that each turn defining a generally cylindrical body is interconnected to one of the adjacent turns so that the turns defining a generally cylindrical body form a longitudinally flexible stent.

Applying these terms of Wiktor's claim 5 to the disclosure of the application under 37 CFR § 1.607(a)(5)(ii)}, reference is first made to page 12, lines 4-17 where, in connection with Wiktor's Fig. 8, it is noted that in an alternative embodiment (one that prevents longitudinal over-stretching) stent 40 has a

generally cylindrical body 42 formed of wire 44. The wire 44 has zigzags or waves 46, certain of which are longer than others; e.g., wave 48. In this embodiment, one out of four of waves 46 is so elongated in the fashion of wave 48 and bent to form a loop or hook 50, each of which is looped over an adjacent wave 46. This engagement with previous waves is disclosed as preventing longitudinal spread of the cylindrical body 42 of stent 40. Fig. 8 thus shows a connection at either the peaks or the valleys of the undulating portion; e.g., element 40 and 50. Lau's claims are broad enough to cover any arrangement in which the elements are merely "interconnected".

It is settled law that once an applicant has selected language which is somewhat broad in its scope, as Lau has done here, he runs the risk that others with specifically different structures may be able to meet the language he selected. Accordingly, he cannot then urge that the language he selected can be read only in the light of his disclosure merely because that language originated with him. *Woods v. Tsuchiya*, 754 F.2d 1571, 1578, *n.* 5, 225 USPQ 11, 15, *n.* 5 (Fed. Cir. 1985); *Hemstreet v. Rohland*, 433 F.2d 1403, 1406, 167 USPQ 761, 763 (CCPA 1970); *Wirkler v. Perkins*, 245 F.2d 502, 505, 114 USPQ 284, 287 (CCPA 1957).

At page 12, lines 13-17, in the discussion concerning Fig. 8, Applicant notes that the function of engagement by hook **50** is to prevent <u>longitudinal overstretching</u>. While the stent of Lau's claim 1 is characterized as possessing "longitudinally flexible", Lau does not affirmatively address *expansion* along the longitude axis of his stent. He does disclose, however, that in one preferred embodiment "there is no shortening of the stent upon expansion." {See, col. 3, lines 5-9; see also, col. 5, lines 50-55}. Since is accomplished by joining the peaks or valleys; *i.e.*, interconnecting, presumably there is no substantial change in the longitudinal dimension of Lau's stent upon radial expansion.

Similarly, both Applicant and Lau affirmatively require that their respective

stents possess the ability to undergo radial expansion, *i.e.*, expansion in the plane defined by the x and y axes perpendicular to the longitudinal axis (the z axis). Moreover both Applicant and Lau achieve their radial expandability in the same fashion, through the use of sinusoidal structures.

In light of this common requirement for radial expansion, the difference between having the sinusoidal pattern on a continuous helical structure having a plurality of turns and having the sinusoidal pattern on three or more circular elements structures which are interconnected would not appear to be significant or material. Thus analytically, both a helix and a circle are defined by the locus of points on a cylindrical surface. The coordinates for those points within a plane of radial expansion, *i.e.*, the plane defined by the *x* and *y* axis, satisfy identical parametric values for both curves.

Thus assuming r is the radius of the cylindrical body and t is the angle of the locus-defining radius from a reference radius, the parametric value of the point relative to the x axis (a coordinate on a first axis perpendicular to the longitudinal (or z) axis of the cylindrical body) is $r \cdot cos t$ for both a circle and a helix. Similarly the parametric value of the point relative to the y axis (a coordinate on a second axis perpendicular to both the z axis and the x axis) for both a circle and a helix is $r \cdot sin t$. Hence the parametric values for the coordinates on the x and y axes are identical for a circle and for a helix.

The difference between a circle and helix lies in the third parametric value, the value of z, the coordinate which falls on the longitudinal or z axis, along which there is no significant expansion. Thus the parametric value of the z coordinate for a circle is 0, producing a plane curve, whereas for a helix the

parametric value of the z coordinate $\neq 0$, producing a twisted curve.⁷ Hence the difference between a circle and a helix would not appear significant for a device that expands radially but not longitudinally.

Lau's claim 2 depends on claim 1 and specifies that the distance between adjacent cylindrically shaped elements is less than the width of either a single peak or a single valley. Applicant's claim 6 states that the distance between adjacent turns defining a generally cylindrical body is less than the width of either a single peak or a single valley.

The basis (description) in Lau's specification for the language of claim 2 cannot be located. Consequently the meaning of "the width of either a single peak or a single valley" cannot be ascertained; *i.e.*, did Lau mean the actual width or was he referring to the amplitude of the sinusoidal figure? Moreover, what distance between adjacent cylindrically shaped elements is being measured. This is particularly difficult to resolve because the undulating patterns of adjacent elements are "out of phase"? Referring to Lau's Figure 11, for example, one can use the minimum distance between proximate peaks and valleys, the maximum distance between distal peaks and valleys, or some average value from the midpoints. A different dimension which may or may not be less than the width of either a single peak or a single valley would result for each.

In any event, applying the terms of Applicant's claim 6 to the disclosure of the application under 37 CFR § 1.607(a)(5)(ii), page 5, lines 30-33, makes specific reference to a sinusoidal form (also referred to as a "zigzag") while on page 6, beginning at line 7, reference is made to then forming a cylindrical

⁷ In a helix, the parametric value of the z coordinate is related to that for the x and y axes, namely $a \cdot t$ where a is constant and t is as defined for x and y coordinates.

shape from the zigzag. The distance between adjacent turns of the helix is less than the width or amplitude of each peak and valley of that zigzag.

Lau's claim 3 depends on Lau claim 1 and specifies that each of the cylindrically shaped elements includes at least three peaks and three valleys. Applicant's claim 7 specifies that each of the turns defining a generally cylindrical body includes at least three peaks and three valleys. Each of the turns in all of Applicant's embodiments includes at least three peaks and three valleys; see, e.g., Figs. 1-8.

Lau's claim 4 also depends on claim 1 and specifies that the peaks and valleys have a substantially U-shaped configuration. Applicant's claim 8 specifies that the peaks and valleys have a substantially U-shaped configuration. Again by definition, the sinusoidal shape of Applicant's "zigzag" necessarily involves a plurality of peaks and a plurality of valleys having a substantially U-shaped configuration.

Lau's claim 5 is an independent claim and contains the same introduction as Lau claim 1, a longitudinally flexible stent for implanting in a body lumen. Applicant's claim 9 similarly recites a longitudinally flexible stent for implanting in a body lumen,

As noted, it is disclosed on page 1, lines 22-25, of Applicant's disclosure that the invention is useful in transluminar implantation of a stent in the field of cardiology and especially in the case of coronary angioplasty to prevent restenosis, on page 4, lines 5 and 6, that prior art stents did not satisfy the requirement of being flexible longitudinally throughout its length, on page 6, line 30, that linear flexibility is an advantage, and on page 7, lines 1-4, that a major object of the invention is a preformed flexible wire stent which allows easy radial expansion and subsequent retention of the radially expanded shape well anchored within a vessel.

Lau's claim 5 next recites the presence of a first cylindrically shaped element,

a second cylindrically shaped element, a third cylindrically shaped element, up to an Nth cylindrically shaped element. The cylindrically shaped elements are generally independently expandable in the radial direction and generally aligned on a common longitudinal axis.

Applicant's claim 9 recites at least three turns defining a generally cylindrical body, the turns being generally independently expandable in the radial direction and generally aligned on a common longitudinal axis.

From page 5, line 27, through page 6, line 12, of his disclosure Applicant discloses that a two dimensional zigzag is wound into a cylindrical shape, *i.e.*, providing a plurality of turns defining a generally cylindrical body. It is further disclosed on page 5, lines 18-22, that this structure can be expanded radially to a diameter larger than initially introduced. Figs. 1-8 all depict at least three turns; *i.e.*, a plurality. Figs. 9-12 show independently expansion of the turns.

Lau's claim 5 next specifies that each of the cylindrically shaped elements has an undulating pattern of peaks and valleys and that the undulating pattern of each of the cylindrically shaped elements is out of phase with the undulating pattern of each of the adjacent cylindrically shaped elements. Applicant's claim 9 recites that each of the turns has an undulating pattern of peaks and valleys and that the undulating pattern of each turn is out of phase with the undulating pattern of each of the adjacent turns

Applying the terms of Applicant's claim 9 to the disclosure of the application under 37 CFR § 1.607(a)(5)(ii)}, page 5, lines 30-33, makes specific reference to a sinusoidal form (also referred to as a "zigzag") while on page 6, beginning at line 7, reference is made to then forming a cylindrical shape from the zigzag. Applicant's Fig. 8 shows the zigzags "out of phase" with each of the adjacent turns.

Lau's claim 5 next specifies that each of the cylindrically shaped elements is interconnected to one of the adjacent cylindrically shaped elements so that the

cylindrically shaped elements form a longitudinally flexible stent. Applicant's claim 9 states that each of the turns is interconnected to one of the adjacent turns so that the turns defining the generally cylindrical body form a longitudinally flexible stent.

Applying these terms of Applicant's claim 9 under 37 CFR § 1.607(a)(5)(ii)}, page 12, lines 4-17 it is noted in connection with Fig. 8 that stent 40 has a generally cylindrical body 42 formed of wire 44 which has zigzags or waves 46. Certain of these are longer than others; e.g. wave 48. In this embodiment, one out of four of waves 46 is so elongated in the fashion of wave 48 and bent to form a loop or hook 50, each of which is looped over an adjacent wave 46. Fig. 8 thus shows a connection at either the peaks or the valleys of the undulating portion; e.g., element 40 and 50. Lau's claims are broad enough to cover any arrangement in which the elements are "interconnected".

Lau's claim 6 depends on claim 5 and states that the distance between adjacent cylindrically shaped elements is less than the width of either a single peak or a single valley. Applicant's claim 10 states the distance between adjacent turns defining a generally cylindrical body is less than the width of either a single peak or a single valley.

. It has already been noted in connection with claim 2 that the meaning of "the width of either a single peak or a single valley" cannot be ascertained since the basis for this terminology cannot be located in Lau's specification. In any event, Applicant makes specific reference to a sinusoidal form (also referred to as a "zigzag") while on page 6, beginning at line 7, reference is made to then forming a cylindrical shape from the zigzag. The distance between adjacent turns defining that cylindrical shape is less than the width or amplitude of each peak and valley of that zigzag.

Lau's claim 7 also depends on claim 5 and states each of the cylindrically shaped elements includes at least three peaks and three valleys. Applicant's

claim 11 specifies each of the turns defining a generally cylindrical body includes at least three peaks and three valleys. The embodiments of Applicant's Figs. 1-8 all depict at least three peaks and three valleys.

Lau's claim 8 also depends on claim 5 and specifies the peaks and valleys have a substantially U-shaped configuration. Applicant's claim 12 states the peaks and valleys have a substantially U-shaped configuration. The sinusoidal shape of Applicant's "zigzag" necessarily involves a plurality of peaks and a plurality of valleys having a substantially U-shaped configuration.

Applicant's claims 5-12 thus (i) are fully supported by the disclosure and (ii) would anticipate or renders obvious the invention defined by Lau's claims 1-8 under the hypothetical assumption set forth in 37 CFR §1.601(n). Similarly the invention defined by Lau's claims 1-8 would anticipate or render obvious the invention defined by Applicant's claims 5-12.

(6) Inapplicability of 35 USC § 112, ¶ 6

For the sake of completeness, Applicant calls the Examiner's attention to the recent decision of the Court of Appeals for the Federal Circuit in *Medtronic, Inc. v. Advanced Cardiovascular Systems, Inc.*, Appeal No. 00-1205, -1214, decided April 20, 2001. Medtronic is the assignee of the present application and Advanced Cardiovascular Systems ("ACS") is the assignee of the Lau patent.

The decision addressed the holding of the District Court for the District of Minnesota that there was no infringement by ACS's product of certain claims in Medtronic's U.S. Patent No. 5,653,727. The application on which that patent issued also claimed the benefit of Serial Nos. 07/327,286 and 07/109,686. The decision addressed claim language under 35 USC § 112, ¶ 6, namely the means-plus-function limitation of "means for connecting adjacent elements together." Because Medtronic had used means-plus-function language in its claims, ¶ 6 of 35 USC § 112 required a determination of the structure associated with that function under *B. Braun Med. Inc. v. Abbott Labs.*, 124 F.3d 1419,

43 USPQ2d 1896 (Fed. Cir. 1997). The District Court had held that the helical winding corresponded to this recited function and not the sutures, straight wire, and hooks that Applicant discloses as preventing longitudinal overstretch. The District Court conceded, however, that the sutures, straight wire, and hooks may, in fact, also perform the function of connecting. While holding these were not "corresponding structure" under ¶ 6 of 35 USC § 112, the Federal Circuit agreed that each structure was capable of performing the recited function.

Since neither Lau's nor Applicant's claims use means-plus-function language, 35 USC § 112, ¶ 6 is not applicable and the *Medtronic, Inc. v. Advanced Cardiovascular Systems, Inc.* opinion is inapposite. Rather, the present situation is governed by the principle noted above, namely that the selection of broad language by an applicant creates the risk that others with different structures may be able to meet that language and if so, he cannot then urge that the language be read only in the light of his disclosure merely because it originated with him. Woods v. Tsuchiya, supra; Hemstreet v. Rohland, supra; Wirkler v. Perkins, supra.

(7) Inapplicability of 35 USC § 135(b)

Finally, claims 5-12 have been presented less than one year after the issue date of U.S. Patent No. 6,066,167, namely May 23, 2000. Consequently, there is compliance with 35 USC § 135(b) and an explanation under 37 CFR §1.607(a)(6) is not required.

Conclusion)

It is respectfully requested that an interference be declared at an early date.

Respectfully submitted, Mathews, Collins, Shepherd & Gould, P.A.

Pruce M. Collins Reg. No. 20,066

May 21, 2001



Appendix 1

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- 5. A linearly flexible stent for implanting within a body vessel {p. 1, II. 22-25; p. 4, II. 5-6; p.6, line 30; p. 7, II. 1-4} comprising:
 - at least three turns defining a generally cylindrical body, the turns being generally independently expandable in the radial direction and generally aligned on a common longitudinal axis{p. 5, I. 27-p. 6, I. 12; p. 5, II. 18-22; Figs. 1-12};
 - each of the turns other than the first and the last having two adjacent turns spaced in opposite axial directions {Fig. 8}
 - each of the turns defining the generally cylindrical body having an undulating pattern of zigzags or waves, each of the turns defining a generally cylindrical body being out of phase with the undulating pattern of each of the adjacent turns defining a generally cylindrical body {p. 5, II. 30-33; p.6, I. 7; Fig. 8}; and
 - each turn defining a generally cylindrical body being interconnected to one of the adjacent turns so that the turns defining a generally cylindrical body form a longitudinally flexible stent {p. 12, II. 4-17}.
- 6. The stent of claim 5, wherein the distance between adjacent turns defining a generally cylindrical body is less than the width of either a single peak or a single valley {p. 5, I. 30-33}.
- 7. The stent of claim 5, wherein each of the turns defining a generally cylindrical body includes at least three peaks and three valleys **Figs. 1-8**.
- 8. The stent of claim 5, wherein the peaks and valleys have a substantially U-shaped configuration **{Figs. 1-8}**.
- 9. A longitudinally flexible stent for implanting in a body lumen, comprising **{p. 1, II.** 22-25; p. 7, II. 1-4};
 - a first turn defining a generally cylindrical body, a second turn defining a generally cylindrical body, a third turn defining a generally cylindrical body, up to an Nth turn defining a generally cylindrical body, the turns being generally



Appendix :

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independently expandable in the radial direction and Generally aligned on a common longitudinal axis {p. 5, I. 27-p. 6, I. 12; p. 5, II. 18-22; Fig. 8};

- each of the turns having an undulating pattern of peaks and valleys, the undulating pattern of each turn being out of phase with the undulating pattern of each of the adjacent turns {p. 5, II. 30-33; Fig. 8}; and
- each of the turns being interconnected to one of the adjacent turns so that the turns defining a generally cylindrical body form a longitudinally flexible stent **{p. 12, II. 4-17}**.
- 10. The stent of claim 9, wherein the distance between adjacent turns defining a generally cylindrical body is less than the width of either a single peak or a single valley {p. 5, I. 30-33}.
- 11. The stent of claim 9, wherein each of the turns defining a generally cylindrical body includes at least three peaks and three valleys **{Figs. 1-8}**.
- 12 The stent of claim 9, wherein the peaks and valleys have a substantially U-shaped configuration **{Figs. 1-8}**.